

## **REMARKS**

### **Status of the Claims**

Claims 1-8 and 14-37 are pending in the application and are presented for examination. Claims 22-37 have been withdrawn from consideration.

### **Withdrawn Rejections**

Withdrawal of the prior rejections under 35 U.S.C. 103(a) is noted with appreciation.

### **Rejection under 35 U.S.C. 103(a)-Carpenter**

Claims 1-6, 14-16 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpenter et al., US 2003/0044354 (Carpenter). Applicant respectfully traverses the above rejection.

For a proper obviousness rejection under 35 U.S.C. 103, the differences between the subject matter sought to be patented and the prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. §103. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. MPEP 2141. “‘[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’” *KSR International Co. v. Teleflex Inc.*, 550 U.S.398, 82 USPQ2d 1385 (2007), quoting *In re Kahn*, 441 F.3d 977, 988, (Fed. Cir. 2006). It should be noted that the prior art reference (or references when combined) must teach or suggest all the claimed features. “When determining whether a claim is obvious, an examiner must make ‘a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art.’ ... Thus, ‘obviousness requires a suggestion of all limitations in a claim.’ ...” *Ex parte Wada and Murphy*, BPAI Appeal No. 2007-3733, January 14, 2008 (emphasis in original) (citations omitted). In addition, there must be a reasonable expectation of success. See MPEP 2143.02.

This standard is not met by Carpenter. For example, it is argued in the Office Action that “since Carpenter et al teach amounts of ... chemical ablation agent (9 % sodium chloride) [in

Example 1] that fall within the ranges cited in the specification, it is the examiner's position that these amounts are effective to cause tissue necrosis..."

In Example 1, however, a "saline glycerol solution (100 ml) was prepared including glycerol (10 ml) and NaCl (680 +/- 2 mg) in water (to a final volume of 100 ml)." Assuming a density of about 1 g/ml (the saline glycerol solution is approximately 90% water), it is found that the solution contains 680 mg (0.680 g) NaCl in approximately 100 g of solution, which corresponds to approximately 0.68% NaCl. The amount is slightly below the level of normal saline (0.9%) and is far below an amount required to cause tissue necrosis as claimed. The amount of NaCl in Example 1 is, however, consistent with the teaching elsewhere in Carpenter regarding the preference to add isotonic agents (see paragraph [0-107]) to the formulations described therein.

For at least the above reasons, it is respectfully submitted that claims 1-6, 14-16 and 19-21 are patentable over Carpenter.

#### **Rejection under 35 U.S.C. 103(a)-Carpenter and Lund**

Claims 7-8 are rejected under 103(a) as being unpatentable over Carpenter as applied to claims 1-6, 14-16, and 19- 21 above and in further view of Lund (US Patent 3,869,546). This rejection is respectfully traversed.

For example, claims 7-8 depend from claim 1 which is patentable over Carpenter for the reasons discussed above. Lund, which is cited for its alleged teachings regarding viscosity, does not make up for the deficiency in Carpenter. Indeed, Lund supports Carpenter's teaching regarding isotonic agents. See, e.g., col. 6, lines 47-49 ("... electrolyte concentration may be as high as that which produces isotonicity in the final injectable solution...").

For at least the preceding reasons, it is respectfully submitted that claims 7-8 are patentable over Carpenter and Lund.

#### **Rejection under 35 U.S.C. 103(a)-Carpenter and Glajch**

Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpenter as applied to claims 1-6, 14-16, and 19-21 above and in further view of Glajch et al., US Patent 5,147,631 (Glajch).

For example, claims 17-18 depend from claim 1 which is patentable over Carpenter for the reasons discussed above. Glajch, which is cited for its alleged teachings regarding ultrasound contrast agents, does not make up for the deficiency in Carpenter.

For at least is reason, it is respectfully submitted that claims 17-18 are patentable over Carpenter and Glajch.

### **CONCLUSION**

Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicant's attorney at 703-433-0510 in order that any outstanding issues be resolved.

Dated: December 12, 2011

Respectfully submitted,

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